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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,226	06/29/2001	Eric J. Benjamin	AM100155	9422

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EXAMINER	
JIANG, SHAOJIA A	
ART UNIT	PAPER NUMBER
1617	9

DATE MAILED: 08/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/896,226	BENJAMIN ET AL.	
	Examiner	Art Unit	
	Shaojia A Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,23 and 25-34* is/are pending in the application.

4a) Of the above claim(s) *15-22 and 24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,23 and 25-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

DETAILED ACTION

This Office Action is a response to Applicant's response filed on June 3, 2003 in Paper No. 7. Currently, claims 1-34 are pending in this application.

As indicated in the previous Office Action December 3, 2002, claims 15-22 and 24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected species. The claims have been examined insofar as they read on the elected specie.

Claims 1-14, 23, and 25-34 are examined on the merits herein.

Merely as an oversight, claims 32-34 were not rejected in the previous Office Action December 3, 2002.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-14, 23, and 25-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (5,780,497, or 5,880,137, or EP 0802184 A1, or EP 0802183 A1, PTO-1449 submitted September 28, 2001) in view of Sawicka (Pharmazie 1991, vol.46 page 519-521, PTO-1449 submitted September 28, 2001).

Miller et al. (5,780,497) discloses that the active substituted indole compounds of the general structural formula therein such as the instant elected compound are useful in pharmaceutical compositions containing a pharmaceutically acceptable carrier or excipients to be administered to a mammal. See for example, '497: abstract, col.2 – col.4, and claims 5-7. Miller et al. also teaches broadly a pharmaceutical carrier or excipient system in a pharmaceutical formulation comprising a filler and disintergrant components, a wetting agent, a lubricant, and a glidant including the instant preferred excipients such as lactose, microcrystalline cellulose, magnesium stearate, and sulfate and Miller et al. teaches that the preparation of the formation comprising the instant compound in various oral forms with these well known excipients is conventional to an ordinary skilled artisan in pharmaceutical science (see especially col.7 lines 23-51).

The prior art does not expressly disclose the employment of the specific range of amounts of a filler and disintergrant components, a wetting agent, a lubricant, and a glidant in a pharmaceutical composition herein. The prior art does not expressly disclose the pharmaceutical composition herein further comprising an antioxidant.

Sawicka teaches that adding an antioxidant to a pharmaceutical composition is well known in the art and the stability of a pharmaceutical formulation may be increase by antioxidant addition. See abstract and the entire article.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to determine the specific range of amounts of a filler and disintergrant components, a wetting agent, a lubricant, and a glidant in a pharmaceutical

composition herein, and to further add an antioxidant to a pharmaceutical composition herein.

One having ordinary skill in the art at the time the invention was made would have been motivated to determine the specific range of amounts of a filler and disintergrant components, a wetting agent, a lubricant, and a glidant in a pharmaceutical composition herein since it is known that a pharmaceutical composition comprising the instant compound and a pharmaceutical carrier or excipient system in a pharmaceutical formulation comprising a filler and disintergrant components, a wetting agent, a lubricant, and a glidant based on the prior art. Moreover, the determination and the optimization of amounts of known exicipients such as a known filler, known disintergrant components, a known wetting agent, a known lubricant, and a known glidant in a pharmaceutical composition are considered conventional to an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Further, one having ordinary skill in the art at the time the invention was made would have been motivated to further add an antioxidant to a pharmaceutical composition herein since adding an antioxidant to a pharmaceutical composition is well known in the art.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Applicant's remarks filed on June 3, 2003 in Paper No. 7 with respect to this rejection of claims 1-14, 23, and 25-31 made under 35 U.S.C. 103(a) of record in the previous Office Action have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art for the following reasons.

Applicant's argument that the there is no motivation or suggestion to determine or optimize the specific range of amounts of a filler and disintergrant components, a wetting agent, a lubricant, and a glidant in the instant claimed composition has been considered but is not found persuasive. As discussed above, the determination and the optimization of amounts of known exicipients such as a known filler, known disintergrant components, a known wetting agent, a known lubricant, and a known glidant in a pharmaceutical composition are considered conventional to an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art. The teachings of Miller et al. regarding that making various formulations comprising the instant compound and those well-known excipients is known to be conventional, clearly support the examiner's position in the rejection.

Moreover, as discussed above, it has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Further, Applicant's Examples 1-9 of the specification at pages 27-32 herein have been fully considered but are not deemed persuasive as to the nonobviousness and/or unexpected results of the claimed invention over the prior art. In this regard, it is

noted that the specification provides no side-by-side comparison with the closest prior art in support of nonobviousness for the instant claimed invention over the prior art.

Therefore, the evidence presented in specification herein is not seen to be clear and convincing in support the nonobviousness of the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. A. Jiang, Ph.D.
Patent Examiner, AU 1617
August 14, 2002

SREENI PADMANABHAN
PRIMARY EXAMINER
8/24/03